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cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on 1H-Isoindole-1,3(2H)-dione, 5, 5'-[(methylethylidene)bis(4,1-phenyleneoxy)]bis[2-methyl- (CAS# 54395-52-7)

(Submitted via Internet 6/29/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Ronald.Joiner@GEP.GE.COM)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 1H-Isoindole-1,3(2H)-dione, 5,5' -[(methylethylidene)bis(4,1-phenyleneoxy)]bis[2-methyl- (CAS# 54395-52-7).

The General Electric Company, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data and proposed testing to address SIDS elements required for 1H-isoindole-1,3(2H)-dione, 5,5' -[(methylethylidene)bis(4,1-phenyleneoxy)]bis[2-methyl-, also known as bisphenol A bisimide. Our review indicates that very little information is provided by this submission. Bisphenol A bisimide is said to be used in the synthesis of high molecular weight polymers. No other background information is provided. (Given that more than one million pounds of this chemical are produced annually, we think General Electric Company could have usefully provided some of what it knows about its production, transport, occupational exposure, etc.)

It appears bisphenol A bisimide has been the subject of very little toxicological or other study. Even the chemical/physical properties appear to be unknown, according to the sponsor. The study/data matrix provided in the test plan proposes that each required SIDS element except acute and repeated dose toxicity, genotoxicity and developmental toxicity/teratogenicity will be addressed by new studies.

The robust summary consists of extensive discussions of those few studies that are available. The studies described appear to be sufficient to address the respective SIDS elements. Studies of acute toxicity are limited to a dermal study in rabbits; however, the repeated dose toxicity studies using doses ranging up to 4% in the diet of rats indicate bisphenol A bisimide has little acute toxicity to mammals. Thus, we do not recommend additional studies of acute toxicity. The developmental toxicity/teratogenicity studies in rats and rabbits used only one dose, but the fact that no effect was observed with an oral dose of 1000 mg/kg indicates bisphenol A bisimide is not teratogenic.

Note: Page 6 of the robust summaries is blank except for the header. It appears that a study of acute toxicity is described on page 6, but it is unavailable for review. The robust summaries should be revised to include this page.

In summary, whereas it is disappointing to see that so little is known regarding an HPV chemical and that General Electric has not provided even the most basic background information on this chemical, we agree that the

present submission should be considered acceptable if all the proposed studies are conducted.

Thank you for this opportunity to comment.

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